IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Michael Radomsky	Attorney Docket No.: DEPYP003D1C1
Application No.: 10/796,441	Examiner: Michael C. Henry
Filed: March 8, 2004	Group: 1623

Title: METHOD OF PROMOTING BONE GROWTH WITH HYALURONIC ACID AND GROWTH FACTORS

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I hereby certify that this correspondence is being transmitted electronically through EFS-WEB to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on October 8, 2007.

Signed: _____/Valerie Olsen/_____
Valerie Olsen

RESPONSE

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action dated April 9, 2007. A three-month extension of time accompanies this response. With the extension, the response is due by October 9, 2007. A Notice of Appeal accompanies this response.

Since this response does not include a change to an existing claim, cancellation of a claim, or submission of a new claim, a claim listing is not required. MPEP 714.

Claims 17-22 are pending in the subject application.

Claims 17, 19 and 20 are rejected under 35 U.S.C. 102(b) as anticipated by Miyoshi et al., (JP04282322), hereinafter "Miyoshi." This rejection is respectfully traversed. In responding to this rejection, Applicant relies upon the Examiner's characterization of the reference, the English abstract appended to the end of the reference, and the enclosed English translation of the reference. It is first pointed out that the present claims are directed to a method. The gel-like consistency

discussed in the specification is important since the composition *is applied at the site of the bone fracture or defect and must persist at that site* for a sufficient period of time as set forth in the specification and in the present claims. In order to persist the site to be effective as claimed, the composition must have a sufficient viscosity and biodegradability to achieve that purpose, as set forth in the claims. Miyoshi does not disclose application of any composition to a bone site and therefore does not recognize the need for persistence at the bone site. Miyoshi does mention that preparations may be made into a solid, liquid or semiliquid gel form (p.4, left column) but that is for formulations for introduction into the bloodstream, presumably by injection or oral intake. The dosage administration is given by mg/kg body weight, which is an indication that introduction into the bloodstream is the mode of delivery to treat the various diseases. Also, see working example 5 (p. 5) where concentration in the blood is discussed. The only topical administration disclosed is as a *liquid solution* for use as drops on the cornea. See working examples 1-4. While gels are discussed, it is apparent that it is the context of making tablets, granules, liquids etc. for oral or parenteral administration. See p.4, left column.

Miyoshi completely misses any recognition of the presently claimed method. Miyoshi does not apply compositions on a site of desired bone growth in order to enhance bone growth there and there is no indication that their compositions could or should be used in that manner. There would be no purpose applying a composition onto a bone defect or injury from any teaching of Miyoshi. Thus, Miyoshi does not anticipate the present claims and it is requested that this rejection be withdrawn.

Claim 18 is rejected under 35 U.S.C. 103(a) as upatentable over Miyoshi. This rejection is respectfully traversed. As stated above, Miyoshi does not apply a composition to a site of desired bone growth. Apart from that point, the Examiner states that the use of compositions containing the same components, but different viscosities, depends on factors such as the severity of bone disease in an individual that is being treated. The Examiner further states that the present claims do not recite that the hyaluronic acid is a gel or in a gel-like state. But nowhere in Miyoshi is viscosity discussed in relation to the severity of bone disease.

Miyoshi is directed preparations generally used for the treatment of conditions such as virus infection, aging, wounds, inflammations and bone diseases. There is no statement in Miyoshi that the composition must be prepared in a certain way to treat a bone disease or even that viscosity is a consideration when treating bone diseases. There is no indication that bone diseases can or should

be treated by directly applying a composition to the bone defect or diseased area and that it must persist there. A fair reading of Miyoshi is that if a bone disease is to be treated, one should take an injection of a liquid or take a tablet or capsule so that the active ingredients may enter the bloodstream.

Accordingly, it is submitted that it would not have been obvious to one of ordinary skill in the art to apply Miyoshi's compositions directly to a bone defect in order to treat a bone disease, much less to modify the viscosity of a composition in any manner for such use.

It is therefore submitted that claim 18 is unobvious over Miyoshi and withdrawal of this rejection is respectfully requested.

Applicant gratefully acknowledges the indication of allowance of the subject matter of claims 21 and 22.

For the foregoing reasons it is submitted that the present application is in condition for allowance. It is appreciated that some of the points above were not apparent and could not be argued until a full translation of Miyoshi could be obtained and studied. In view of the translation, it is submitted that the Examiner can better appreciate the deficiencies in the teachings of Miyoshi and thus will pass the application to issuance.

If prosecution of this application can be expedited by a telephone conference, the Examiner is requested to call Applicant's undersigned attorney at (510) 663-1100.

Please apply any other charges or credits to deposit account number 50-388 (Order No. DEPYP003D1C1).

Dated: October 8, 2007

Respectfully submitted,
BEYER WEAVER, LLP

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